toXcel

Toxicology & Regulatory Affairs 7140 Heritage Village Plaza Gainesville, VA 20155-3061 USA

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November 25, 2020

Jeannine Kausch PM 92 (REGFEE)
Biopesticides and Pollution Prevention Division (Mail Code 7511P)
US EPA / Office of Pesticide Programs
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: Efficacy Protocol for Testing Against SARS Cov-2 and Other Viruses

EPA Company Number: 94339

PRIA Category: A521

Dear Ms. Kausch:

On behalf of our client, Better Air International, Ltd, and per our teleconference on November 4, 2020 with the Antimicrobial Division (Efficacy Branch) we are hereby submitting an efficacy testing protocol for Agency review. The purpose of this protocol is to demonstrate activity against viruses (including SARS Cov-2) using the currently pending product EB-8 (EPA File Symbol 94339-R). We understand that this submission has no bearing on the registration application currently being reviewed by the Agency and that data conducted under this protocol may be submitted in support of future efficacy labelling claims once the Agency has had an opportunity to review and comment on the protocol.

The following are included with this registration application package:

- 1. Registration Application (EPA Form 8570-1)
- 2. PRIA Payment Confirmation
- 3. Transmittal Document
- 4. Study Protocol
- 5. Data Matrix (EPA Form 8570-35) Public and Private versions
- 6. Respect for Citation of Data
- 7. Copy of EPA Acceptance Letter for Small Business Waiver (dated April 9, 2020)
- 8. Company Certification Letter
- 9. PRIA Payment receipt

It is anticipated that this submission will be categorized as an A521, with a 4-month EPA review timeframe and an associated fee of \$4963.00 (\$1,240.75 w/the small business discounted fee). Better Air International, Ltd. received its small business waiver earlier this year. Included with this submission is a copy of the EPA acceptance letter and the company certification stating that there have been no changes to the company's financial or employee status since the waiver was approved.

If you have any questions or require additional information, please do not hesitate to contact me. I can be reached via e-mail at Connie.Welch-DuJardin@toxcel.com or by phone at (703) 754-0248 x 8118.

Sincerely,

Dr. Cari B. Welet-Defords Dr. Connie Welch-DuJardin

Vice President